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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-16-16PA; Docket No. CDC-2016-0021]**

**Proposed Data Collections Submitted for Public Comment and  
Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the Study to Explore Early Development (SEED) Phase 3.

**DATES:** Written comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2016-0021 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.

- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

**FOR FURTHER INFORMATION CONTACT:** Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 6501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of the information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of the information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB

for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on:

- (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;
- (b) the accuracy of the agency's estimate of the burden of the proposed collection of information;
- (c) ways to enhance the quality, utility, and clarity of the information to be collected;
- (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and
- (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to

respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

### **Proposed Project**

Study to Explore Early Development 3 (SEED 3) - New - National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

Autism spectrum disorders (ASD) are a group of neurodevelopmental disorders characterized by qualitative impairments in social interaction and communication and stereotyped behaviors and interests. Recent systematic population surveys and routine monitoring systems in the US and other countries indicate the prevalence to be 1% to 2%. Apart from the identification of some rare genetic conditions that are commonly associated with autism, causal mechanisms for the disorder largely remain unknown.

The Children's Health Act of 2000 mandated CDC to establish autism surveillance and research programs to address the number, incidence, and causes of autism and related developmental disabilities. Under the provisions of this act, NCBDDD funded

five Centers for Autism and Developmental Disabilities Research and Epidemiology (CADDRE) through program announcements in FY2001 and FY2002 (California, Colorado, Maryland, North Carolina and Pennsylvania); CDC's NCBDDD served as the sixth CADDRE site.

For the first funding cycle (2001-2006), each CADDRE grantee had three core objectives: to develop a protocol for a multi-site collaborative epidemiologic study focused on autism (which was eventually named the Study to Explore Early Development [SEED]); to conduct surveillance of autism and other developmental disabilities; and to conduct site-specific investigator-initiated studies on autism. In FY 2006, through a second CADDRE funding cycle, five grantees were awarded. The CADDRE activities for the second funding cycle (2006-2011) were limited to implementation of the first phase of SEED (subsequently known as SEED 1). CDC served as the sixth CADDRE SEED 1 site during this period. A second phase of SEED (SEED 2) was funded under a third funding cycle (2011 - currently ongoing with completion in 2016). Five CADDRE grantees received the awards. Again, CDC served as the sixth SEED 2 site.

Four extramural sites plus the CDC site will implement the SEED 3 collaborative protocol. The SEED 3 protocol for identification of study participants, recruitment, and study data collection flow will be very similar to the protocols for

SEED 1 and 2.

Modifications that will be implemented in the third round of data collection include recruitment from a more recent cohort of children, strategies to improve response rates, and a further reduction in the data collection protocol. No data collection instruments/exams used in SEED 2 will be revised in SEED 3; however, some instruments will not be retained in the protocol to reduce participant burden.

Families will be identified from each of the 3 groups: Autism Spectrum Disorder (ASD), other developmental delay or disorder comparison group (DD), and a second comparison group of children randomly drawn from the entire study cohort population (POP). It is expected that the 5 SEED 3 study sites will have a total of 1,875 children enroll and complete the study protocol. The data collection process will take approximately 9 hours 10 minutes (ASD group); 5 hours 30 minutes (POP group); 2 hours 45 minutes (DD group) to complete, which includes 1) maternal telephone interview with questions about maternal reproductive history and pregnancy with the index child, 2) parent-completed questionnaires about parental and child health and child development, 3) in-person child developmental evaluation, 4) maternal and child anthropometry measurements, 5) biosampling from biological parents and child, and 6) abstraction of maternal prenatal and labor and delivery medical records. The

estimated total burden hours are 18,431. There are no costs to participants other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Parent	SCQ	1,875	1	30/60	938
Parent	Pregnancy Reference form	1,875	1	15/60	469
Parent	Maternal Interview	1,875	1	60/60	1,875
Parent	Self-Administered Forms	1,875	1	88/60	2,750
Parent	HIPAA Medical Records Release	1,500	1	20/60	500

Parent / Child	Clinic / Home Visit - Developmental Assessment	3,000	1	238/60	11,900
TOTAL		12,000			18,431

**Leroy A. Richardson,**

*Chief, Information Collection Review Office,  
Office of Scientific Integrity,  
Office of the Associate Director for Science,  
Office of the Director,  
Centers for Disease Control and Prevention.*

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